

## **REMARKS**

Claims 46-59 and 61-68 were pending in the present application. Claims 53 and 55-57 have been canceled without prejudice. Applicants reserve the right to pursue the subject matter of the canceled claims in one or more related applications.

Claim 46 has been amended to clarify that which Applicants regard as the invention. Specifically, claim 46 has been amended to delete recitation of "Polysorbate" and "Triton X-100." These amendments are made without prejudice. Applicants reserve the right to prosecute the deleted subject matter in related applications.

Claims 58 and 59 have been amended to depend upon any of claims 46-53. Support for this amendment may be found in the specification, for example, at page 10, line 31 to page 11, line 11. Claim 58 has also been amended to correct a grammatical error. Claim 59 has also been amended to specify that the excipient is hydroxypropyl- $\beta$ -cyclodextrin. Support for this amendment may be found in the specification, for example, at page 11, lines 1-10.

Claims 65 and 67 have been amended to delete dependency upon canceled claim 56, and in order to avoid having a multiply dependent claim depend upon a multiply dependent claim (claim 58). Claim 67 has also been amended to be dependent upon claim 51. Support for this amendment may be found in the specification, for example, at page 11, line 30 to page 12, line 7.

New claim 69 has been added to replace the dependency upon claim 58 that was deleted from claim 65. New claims 69 and 70 encompass additional embodiments which Applicants regard as the invention. Support for new claim 69 may be found in the specification, for example, at page 11, line 17. Support for new claim 70 may be found in the specification at page 12, lines 5-6.

No new matter has been added by these amendments. Upon entry of these amendments, claims 46-52, 54, 58-59 and 61-70 will be pending in the present application.

Since the claims no longer recite non-ionic surfactants, which were elected as a species in Applicant's Response to Restriction Requirement Under 37 C.F.R. § 1.143 filed on November 19, 2004, Applicants' respectfully request that the species election be changed to  $\beta$ -cyclodextrin.

Applicants respectfully request that the amendments and remarks made herein be entered and fully considered.

## **INTERVIEW SUMMARY RECORD**

Applicants and Applicants' representatives wish to thank Examiner Yunsoo Kim for the courtesy of the telephone call of April 11, 2006 with Applicant's representative, Adriane M. Antler, in connection with the above-referenced application.

During the telephone call, Dr. Antler informed Examiner Kim of our intent to delete "Polysorbate" and "Triton X-100" from the claims and that we wished, in effect, to change our species election to  $\beta$ -cyclodextrin. Examiner Kim stated that this would be acceptable, but that she would have to search  $\beta$ -cyclodextrin for prior art.

### **The Rejection Under 35 U.S.C. § 102(e) Should be Withdrawn**

Claims 46, 49-53, 56, 57 and 63-68 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,146,632 (the "'632 patent"). The Examiner contends that the '632 patent teaches an immunogenic composition comprising an antigen and QS-21 in an oil-in-water emulsion containing a polysorbate.

In response, Applicants have amended the claims to delete reference to a polysorbate. Since the '632 patent does not teach  $\beta$ -cyclodextrin or deacylsaponin, the '632 patent does not anticipate the claims as amended. Accordingly, the rejection has been obviated.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102(e).

### **The Rejection Under 35 U.S.C. § 103(a) Should be Withdrawn**

Claims 46-48 were rejected 35 U.S.C. § 103(a) as allegedly being obvious over the '632 patent in view of U.S. Patent No. 5,057,540 (the "'540 patent"). The '632 patent has been discussed above. The Examiner contends that the '540 patent teaches Quil-A is readily available and shows good adjuvant activity.

The legal standard for nonobviousness was presented in Applicants' Amendment Under 37 C.F.R. 1.111 filed on April 11, 2005.

In response, Applicants have amended the claims to delete reference to a polysorbate. As discussed above, the '632 patent does not teach  $\beta$ -cyclodextrin or deacylsaponin. The '540 patent does not teach or suggest  $\beta$ -cyclodextrin. The '540 patent teaches that alkaline hydrolysis of a crude *Quillaja saponaria* (QS) saponin mixture resulted in deacylsaponins, but that such deacylsaponins lack adjuvant activity ('540 patent at col. 2, lines 5-17, col. 16, lines 27-39 [Example 7] and col. 22, lines 36-49 [Example 15]). Since

Example 15 of the '540 patent shows that deacylsaponins lack adjuvant activity, the '540 patent teaches away from the use of deacylsaponins as an adjuvant. Moreover, there is no suggestion or motivation in the '540 patent to use deacylsaponins in a method for enhancing an immune response for any other reason. Thus, neither the '632 patent nor the '540 patent, alone or in combination, provide any suggestion or motivation in the '540 patent to use a deacylsaponin as an excipient in combination with a QS saponin in a method for enhancing an immune response.

The '632 patent, alone or in combination with the '540 patent, does not render obvious the presently claimed invention. Accordingly, the rejection has been obviated.


In view of the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103(a).

#### **CONCLUSION**

Applicants respectfully request that the present amendments and remarks be made of record in the instant application. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Respectfully submitted,

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